



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/030,464 | 05/22/2002 | Ivo Feussner | 215110 | 8403 |
| 23460 | 7590 | 10/06/2004 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780 | | | PAK, YONG D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/030,464 | Applicant(s) FEUSSNER ET AL. | |
| | Examiner Yong D Pak | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-28 is/are pending in the application.
- 4a) Of the above claim(s) 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/24/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/EP00/06539.

Claims 12-18 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on June 28, 2004 is acknowledged. In the response filed on April 12, 2004, applicants did not clearly indicate an election of Group I. The traversal is on the ground(s) that Groups I and II share a special technical feature. This is found persuasive and claims 18-23 have been rejoined with Group I. However, claims 24-25 are drawn to a transgenic plant and do not share a special technical feature. Even though the transgenic plant comprises the cell comprising DNA encoding a mutant plant lipoxygenase, the transgenic plant is living organism comprising functions and structures unrelated to the mutant lipoxygenase.

Claims 24-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 28, 2004.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 24, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of enhancing specificity for position 11 of arachidonic acid by mutating a residue corresponding to position 576 of a potato tuber lipoxygenase and the mutant lipoxygenase and DNA encoding said lipoxygenase obtained by said method. Therefore, these claims are drawn to a genus of mutant lipoxygenase. There are many isoforms in the family of lipoxygenases and even in potato tuber, there are multiple forms of lipoxygenase isoenzymes (Mulliez et al. – form PTO-1449). However, the specification only teaches one representative species of a mutant lipoxygenase with an enhance specificity towards position 11 of arachidonic acid, a 5-lipoxygenase derived from potato tuber (accession S73865) wherein a

Art Unit: 1652

threonine at position 576 has been modified with a phenylalanine residue (Table 1 on page 4 of the specification). One species is not enough to describe the whole genus of possible mutant plant lipoxygenase and there is no evidence on the record of the relationship between the structure of a 5-lipoxygenase from potato tuber and the structure of any plant lipoxygenase from another source and there is no evidence on the record of the correlation between any plant lipoxygenase comprising a mutation at position 576 and an enhanced specificity towards position 11 of arachidonic acid. Therefore, the specification fails to describe a representative species of the genus of mutant plant lipoxygenase.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 12-23.

Claims 12-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a 5-lipoxygenase derived from potato tuber (accession S73865) having a Phe at position 576 and DNA encoding said mutant enzyme and a method of enhancing the specificity for position 11 of arachidonic acid of a 5-lipoxygenase derived from potato tuber (accession S73865), does not reasonably provide enablement for a method of enhancing the specificity of position 11 of arachidonic acid by mutating position 576 of any plant lipoxygenase or the mutant lipoxygenase obtained by said method or DNA encoding said mutant. The specification

Art Unit: 1652

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

To practice the invention, the structure of the plant lipoxygenase must be known. However, the specification only teaches a few lipoxygenases. However, there are many isoforms of the enzyme and even within potato tuber, there are multiple isoforms, as discussed above. Despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other lipoxygenases whose sequence is different to the few examples of lipoxygenase taught on page 4 of the specification. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other lipoxygenase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino

acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of all lipoxygenase. It would require significant study to identify any lipoxygenase and would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Further, the invention is drawn to a method of enhancing specificity for position 11 of arachidonic acid by mutating a residue corresponding to position 576 of a lipoxygenase derived potato tuber. However, there is no clear record that mutating position 576 of any plant lipoxygenase will enhance the specificity for position 11 of arachidonic acid. The specification only teaches an enhanced specificity towards position 11 of arachidonic acid in a lipoxygenase comprising a mutation a position 576 in the 5-lipoxygenase derived from potato tuber.

Therefore, one of ordinary skill would require guidance in order to enhance specificity toward position 11 of arachidonic by mutating position 576 of any plant lipoxygenase and to make a plant mutant lipoxygenase having enhance specificity towards position 11 of arachidonic and DNA encoding said mutant in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In potato tuber, there are multiple isoforms of the enzyme. Therefore, without the recitation of the SEQ ID NO of the potato lipoxygenase, it is unclear which residue corresponds to position 576. Further, even if the exact isoform is indicated in the claims, depending on whether the initial Met residue is present in the sequence, the residue at position 576 can be different.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner


